REMARKS

Claims 1-11 were rejected under 35 U.S.C. § 112, first paragraph. Claims 9-11 were rejected under 35 U.S.C. § 112, second paragraph. Claims 1 and 3 were rejected under 35 U.S.C. § 102(b). Claims 1-4 and 11 were rejected under 35 U.S.C. § 103(a). Each of these rejections is addressed as follows.

Amendments

Claims 1, 2, 9, 10, and 11 have been amended. These amendments find support throughout the specification. For example, claims 1 and 2 have been amended to recite that the claimed vaccine induces a cellular immune response specific to a virus protein encoded by a Sendai virus vector comprised in the vaccine. Support for this amendment is found in the specification, for example, at page 10, lines 5-6 and 27-29.

In addition, new claims 12-45 have been added.

Support for claims 12-15 is found in the specification, for example, at page 17, lines 11-12; page 21, line 30 to page 23, line 7; page 41, lines 13-19; page 42, lines 16-18; and Example 6.

Support for claims 16-19 is found, for example, at page 10, lines 3-9 and 27-29; page 17, lines 11-12; page 21, lines 9-17; page 21, line 30 to page 23, line 7; and page 36, line 22 to page 37, line 3.

Support for claim 20 is found, for example, at page 41, lines 3-5; page 42, lines 8-9; and Example 7. Support for claims 21-32 is found in the specification, for example, at

page 17, lines 11-12; page 21, line 30 to page 23, line 7; page 38, lines 25-31; page 39, lines 1-21; page 40, line 11 to page 41, line 2; Example 9; and Table 5.

Support for claim 33 is found, for example, at page 37, lines 4-6; and Examples 4 and 9. Support for claims 34-45 is found, for example, at page 17, lines 11-12; page 21, line 30 to page 23, line 7; page 38, lines 25-31; page 39, lines 1-21; page 40, line 11 to page 41, line 2; Example 9; and Table 5.

No new matter has been added.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-11 stand rejected under § 112, first paragraph, for lack of enablement. This rejection is respectfully traversed.

Claims 1-4 are directed to a vaccine, and claims 5-10 are directed to a method for vaccination. These claims are supported, for example, by the description found at page 18, lines 6-12; page 35, line 28 to page 21; page 37, lines 4-25; and page 38, line 16 to page 40, line 21. From this description, one skilled in the art could readily practice the claimed invention without undue experimentation.

Claim 11 is directed to a method for inducing a cellular immune response specific to a virus protein of an immunodeficiency virus. As the Examiner acknowledges, "the specification teaches . . . using [Sendai virus vectors encoding SIV-Gag protein] to induce an antigen-specific cellular immune response *in vitro*, and *in vivo* by intranasal administration in cynomolgus macaques." (See, for example, page 3, lines 17-20, of the

Office Action). Moreover, the specification indeed teaches the claimed method (see Examples 3, 6, and 7). Accordingly, one skilled in the art could practice the claimed invention without undue experimentation.

Indeed, the leading Federal Circuit decision applying the undue experimentation standard in the field of biotechnology, *In re Wands*, 858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988), supports applicants' position on this point. The enablement issue in *Wands* related to whether the amount of experimentation required to obtain hybridomas that produced an antibody for use in a claimed immunoassay was undue, and thus negated enablement. In reversing the Examiner's decision on this issue, the Court noted that the amount of experimentation is not necessarily decisive in a determination of enablement, if the type of experimentation is merely routine or if the specification provides guidance as to how the experimentation should proceed. Indeed, the Court noted that even if only 2.8% of hybridomas screened were found to produce a useful antibody, the enablement requirement would still have been met, because the methods used to screen them were routine, and the level of skill in the relevant art was high.

The same is true in the present case: routine challenge models were available for determining the efficacy of an antigen, as well as described in the specification, and their use was routine. Moreover, the level of skill in this art is quite high, with many researchers holding advanced scientific or medical degrees. Further, the number of possible hybridomas *in Wands* could be considered to be infinite, while the number of possible antigens for use in the present methods is far more limited, especially in light of

the present amendment. Thus, it is applicants' position that it would not have required undue experimentation to produce any of the claimed compositions or to carry out the claimed method, and that also it would not have required undue experimentation to identify other immunodeficiency virus antigens for use in the claims.

Moreover, determination of what constitutes an effective amount of a vaccine antigen for a particular subject, such as a human, is a standard practice for medical professionals and can be carried out in the absence of undue experimentation.

The Examiner also cites several references in support of this rejection, which, according to the Examiner, show that immunodeficiency virus vaccination is, in essence, unpredictable.

For example, the Examiner refers to several passages from Ourmanov, including a statement that "the level of protection from AIDS was clearly less than optimal." Regardless of what the Ourmanov reference taught in 2000, it is not relevant to the state of the Sendai virus vaccine art at the time applicants field their application. Similarly, citing the McCluskie reference, the Examiner notes that the vaccine art includes the statement that "the promising results in animal models have not been realized in human trials." Like Ourmanov, McCluskie is not relevant to the Sendai virus vaccine art.

Furthermore, reliance on these references to demonstrate that an AIDS vaccine is still under development, requiring trial and error experimentation, is also improper. Under the case law, clinical efficacy is not required to show that a therapeutic compound or process has utility (M.P.E.P. § 2107). As is stated in § 2107.01 of the M.P.E.P.,

"courts have found utility for therapeutic inventions, despite the fact that an applicant is at a very early stage in the development of a therapeutic regimen," or that a therapeutic compound or treatment regimen is not at a stage where it is ready to be practiced upon humans. *Cross v. Iizuka*, 753 F.2d 1040, 224 U.S.P.Q. 739 (Fed. Cir. 1985), *In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995).

Furthermore, it is not within the province of the PTO to require proof of efficacy in humans to grant a patent including claims to therapeutic methods. The PTO guidelines, in fact, are explicit on the point: "Office personnel should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention relating to treatment of human disorders..." (M.P.E.P. § 2107.03). Further on this point, the guidelines state that "[t]he Office must confine its review of patent applications to the statutory requirements of the patent law," and, in quoting *In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995), that "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." *Id.*

The rejection under § 112, first paragraph, should therefore be withdrawn.

Rejections Under 35 U.S.C. § 112, second paragraph

Claims 9-11 stand rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness, which are addressed as follows.

Claims 9 and 10 were deemed vague and indefinite in reciting "inoculating a DNA vaccine." To clarify what is meant by this phrase, applicants have amended these claims to refer to the step of "inoculating a DNA vaccine comprising a DNA encoding the genome of an immunodeficiency virus." Support for this amendment is found in the specification, for example, at page 13, lines 24-25; and page 40, lines 15-16.

Claim 11 was rejected as incomplete and unclear. This basis for the rejection has been met by the current, clarifying amendment. By this amendment, Applicants have specified an "*in vitro*" method for inducing "a cellular immune response." In addition, the claim now recites a positive step that relates back to the preamble.

Accordingly, in view of applicants' amendment, the indefiniteness rejection of claims 9-11 may be withdrawn.

Rejection Under 35 U.S.C. § 102(b)

Claims 1 and 3 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Yu et al. (Genes Cells 2:457-66, 1997). As applied to the present claims, this rejection is respectfully traversed.

As an initial matter, applicants point out that these claims were also rejected in the present Action under 35 U.S.C. § 103. In making that rejection, the Office found it necessary to combine Yu with Flanagan et al. (J. Gen. Virol. 78:991-7, 1997), calling into question the legitimacy of the Office's position on anticipation. Based on this acknowledgment by the Office alone, the § 102 rejection should be withdrawn.

Moreover, the rejection should also be withdrawn because Yu fails to provide all of the elements of the presently claimed invention. The claims, as amended, now require that the virus protein comprises a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them. Support for this amendment is found in the specification, for example, at page 17, lines 11-12; and page 21, line 30 to page 23, line 7. This group of viral proteins is distinct from anything disclosed by the Yu reference. The § 102 rejection should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yu et al. (Genes Cells 2:457-66, 1997) in view of Flanagan et al. (J. Gen. Virol. 78:991-97). Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinman et al. (U.S. Patent No. 6,300,090) in view of Yu et al. (Genes Cells 2:457-66, 1997) and Seth et al. (Proc. Natl. Acad. Sci. USA 95:10112-6, 1998). These rejections are respectfully traversed.

Claims 1-4

Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yu et al. (Genes Cells 2:457-66, 1997) in view of Flanagan et al. (J. Gen. Virol. 78:991-97). This basis of the rejection is respectfully traversed.

The § 103 rejection is traversed because the references cited by the Office do not alone or in combination support a *prima facie* case of obviousness for these claimed

methods. To make out such a *prima facie* case, the Patent Office must show that "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a) (emphasis added). The framework for making such a determination was set out by the United States Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966):

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. *ASC Hospital Systems, Inc. v. Montefiore Hospital,* 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). This suggestion or motivation may be derived from the prior art reference itself, from the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *Sibia Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349 (Fed. Cir. 2000). The basis for a prior art combination, however, must come from a source other than the inventor's disclosure. The Court of Appeals for the Federal Circuit has repeatedly emphasized that hindsight analysis is an inappropriate means for piecing together the elements of an invention from unrelated references. For example, in *In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780

(Fed. Cir. 1992), the Federal Circuit stated:

> It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious.

And in *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 227 U.S.P.Q. 543 (Fed. Cir. 1985), the court stated:

> It is error to reconstruct the patentee's claimed invention from the prior art by using the patentee's claim as a "blueprint." When prior art references require selective combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight obtained from the invention itself.

In short, to support an obviousness rejection of the present claims, the prior art must supply each and every element of the method steps in the order recited, and, if references are combined, the basis for this combination must be obtained from a source other than Applicants' invention. Applying these standards to the present case, it is clear that the § 103 rejection may be withdrawn.

Taking each reference in turn, Yu, the primary reference describes Sendai virus-based expression of HIV-1 gp120.

As the Examiner correctly states, Yu fails to teach applicants' claimed invention because this reference fails to disclose one of the invention's central features: namely, expression of a Gag protein, using a Sendai virus vector, to induce cellular immunity. Moreover, Yu also fails to disclose or suggest that a vaccine that includes a Sendai virus vector encoding a virus protein of an immunodeficiency virus could induce a cellular immune response specific to the virus protein.

The Examiner attempts to cure the deficiencies of Yu by citing the teachings of Flanagan. Flanagan is cited as teaching a vector encoding SIV Gag protein.

Flanagan, however, like Yu, fails to teach or suggest applicants' claimed invention. Flanagan fails to teach or suggest a Sendai virus vector encoding a virus protein of an immunodeficiency virus. Flanagan also fails to teach or suggest that a vaccine comprising the Sendai virus vector could induce a cellular immune response specific to the virus protein.

In view of the above, it is clear that neither Yu nor Flanagan, alone or in combination, teach or suggest applicants' claimed invention because each of these references lacks one or more of the important features of applicants' novel vaccine. In combining these references, the Examiner contends that it would be obvious to modify the vector described by Yu with the Gag protein described by Flanagan. However, as is discussed above, there is no suggestion or incentive to combine the teachings of these references, as is required for a combination of references to support an obviousness rejection under § 103. None of the cited references, alone or in combination, teaches that applicants' claimed invention might be possible or desirable. In fact, in reading the cited references, it appears that the authors of the Flanagan reference were satisfied with the vectors that they had in hand. There is no suggestion that their vectors could be improved, that vectors like those of the presently claimed invention were needed, or that the material taught in the references should be combined. The obviousness rejection of claims 1-4 should therefore be withdrawn.

Claim 11

Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Steinman et al. (U.S. Patent No. 6,300,090) in view of Yu et al. (Genes Cells 2:457-66, 1997) and Seth et al. (Proc. Natl. Acad. Sci. USA 95:10112-6, 1998). This rejection is respectfully traversed.

In essence, the Office Action bases this rejection on a combination of three references that, individually, suggest or describe isolated aspects of applicants' claimed invention. These references were combined using hindsight from applicants' teaching, which is not permissible.

It is applicants' position that nothing in Steinman, Yu, or Seth suggests the desirability of a combination leading to the claimed invention, and these references cannot therefore render the present invention obvious. As is discussed below, nothing in the record provides so much as a single suggestion of applicants' claimed invention. This is especially significant, given the fact that, at the time of applicants' invention, it was a major goal of the art to improve vaccines for immunodeficiency viruses. Yet not in a single one of these documents did the authors make the slightest mention of even the possibility of modifying their own approaches. Indeed, all of the evidence demonstrates that the scientists of the disclosed prior art methods were content with the methods each had developed and utilized. The possibility of using applicants' claimed invention was simply not mentioned in the scientific literature, let alone the references of record.

Taking each reference in turn, Steinman is cited for "teach[ing] a method

comprising providing antigens to dendritic cell (APC) using a viral vector including Sendai virus..." Steinman, however, at col. 18, ll. 37-40, only discloses that "[i]n addition to influenza virus, dendritic cells are specialized APCs for the presentation of several other viruses to T cells, including ... Sendai virus (28) in the mouse," by citing the reference Kast et al. (*J. Immunol.* 140: 3186-3193, 1988; copy enclosed). Based on this teaching, Steinman fails to suggest or teach using a Sendai virus in their disclosed method. In addition, because Kast fails to disclose or suggest a Sendai virus encoding a virus protein of an immunodeficiency virus, Steinman also fails to disclose or suggest such a Sendai virus. Consequently, Steinman fails to disclose or suggest a method for inducing a cellular immune response specific to a virus protein of an immunodeficiency virus using a Sendai virus vector encoding a virus protein of an immunodeficiency virus.

The secondary references provided by the Office do not cure the considerable deficiencies in the Steinman teaching.

Yu, as discussed above, discloses Sendai virus-based expression of HIV-1 gp 120. Yu is relied upon by the Office for teaching that the Sendai virus vector system might be used for vaccine development. Yu teaches that a Sendai virus vector encoding gp120 of the human immunodeficiency virus might be used for broad applications (page 463, right column, lines 19-22 and 29-31) and is important for vaccine development (page 457, right column, lines 4-5). Yu, however, fails to disclose or suggest that a vaccine comprising a Sendai virus vector encoding a virus protein of an immunodeficiency virus could induce cellular immune response specific to the virus protein.

Finally, Seth fails to disclose or suggest a Sendai virus vector encoding a virus protein of an immunodeficiency virus and a method for inducing cellular immune response specific to the virus protein using the Sendai virus vector.

In short, none of these references discuss methods for inducing a cellular immune response specific to a virus protein of an immunodeficiency virus *in vitro* involving the steps of (a) introducing a Sendai virus vector encoding the virus protein into an antigen presenting cell and (b) contacting the antigen presenting cell with a T helper cell and a cytotoxic T cell, thereby inducing the cellular immune response. Accordingly, none of these references can provide the requisite motivation needed for combining the teaching with the Steinman patent.

Furthermore, even if combined with Steinman, these combined references fail to provide the presently claimed invention. None of Steinman, Yu, Seth teaches or suggests the use of a Sendai virus for inducing a cellular immune response. Accordingly, this combination of references cannot suggest applicants' invention.

In view of the above, Applicants request that the § 103 rejection, as applied to claim 11, be withdrawn.

Conclusion

Applicants submit that this case is in condition for allowance, and such action is respectfully requested.

Applicants note that the Forms PTO-1449 that were submitted with Information Disclosure Statements filed on July 24, 2001 and June 6, 2002 have not been initialed and returned, and hereby request that they be initialed and returned with the next Office action.

Enclosed is a Petition for Extension of Time and a check in the amount of $460.00 for the required fee. Also enclosed is a check in the amount of $330.00 for the newly added independent and dependent claims.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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James D. DeCamp, Ph.D.
Reg. No. 43,580

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

U.S. Serial No. 09/823,699

Version of Claims Showing Changes Made

Claims 1, 2, 9, 10, and 11 were amended as follows.

1. (Amended) A vaccine comprising a Sendai virus vector encoding a virus protein of an immunodeficiency virus, wherein the virus protein comprises a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them, and wherein the vaccine induces a cellular immune response specific to the virus protein.

2. (Amended) [The] A vaccine [of claim 1, wherein the virus protein comprises] comprising a Sendai virus vector encoding a Gag protein or a part of it, wherein the vaccine induces a cellular immune response specific to the Gag protein or the part of it.

9. (Amended) The method of claim 7, wherein the method comprises the steps of (a) inoculating a DNA vaccine comprising a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector encoding a virus protein of an immunodeficiency virus.

10. (Amended) The method of claim 8, wherein the method comprises the steps of (a) inoculating a DNA vaccine comprising a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector

encoding a virus protein of an immunodeficiency virus.

11. (Amended) A method for inducing a cellular immune response specific to a virus protein of an immunodeficiency virus *in vitro*, the method comprising the steps of (a) introducing a Sendai virus vector encoding [a] the virus protein [of an immunodeficiency virus] into an antigen presenting cell and (b) contacting the antigen presenting cell with a T helper cell and a cytotoxic T cell, thereby inducing the cellular immune response.

The following new claims 12-45 were added.

12. (New) The method of claim 11, wherein the virus protein comprises a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them.

13. (New) The method of claim 11, wherein the virus protein comprises Gag protein or a part of it.

14. (New) The method of claim 11, wherein the antigen presenting cell is an autologous herpesvirus papio-immortalized B lymphoblastoid cell.

16. (New) A composition comprising a carrier and a Sendai virus vector encoding a virus protein of an immunodeficiency virus, wherein the virus protein comprises a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them, and wherein the vaccine induces cellular immune response specific to the virus protein.

17. (New) A composition comprising a carrier and a Sendai virus vector encoding Gag protein or a part of it, wherein the vaccine induces cellular immune response specific to the Gag protein or the part of it.

18. (New) The composition of claim 16, wherein the Sendai virus vector is defective in V gene.

19. (New) The composition of claim 17, wherein the Sendai virus vector is defective in V gene.

20. (New) A method for inducing cellular immune response specific to a virus protein of an immunodeficiency virus in an animal, the method comprising inoculating a composition comprising a carrier and a Sendai virus vector encoding the virus protein.

21. (New) The method of claim 20, wherein the composition is inoculated by intranasal administration.

22. (New) The method of claim 20, wherein the composition is inoculated at least once by multiple dose administration.

23. (New) The method of claim 21, wherein the composition is inoculated at least once by multiple dose inoculation.

24. (New) The method of claim 22, wherein the method comprises the steps of (a) inoculating a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector.

25. (New) The method of claim 23, wherein the method comprises the steps of (a) inoculating a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector.

26. (New) The method of claim 24, wherein the genome is defective in env gene and nef gene.

27. (New) The method of claim 25, wherein the genome is defective in env gene and nef gene.

28. (New) The method of claim 20, wherein the virus protein comprises a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them.

29. (New) The method of claim 20, wherein the virus protein comprises Gag protein or a part of it.

30. (New) The method of claim 20, wherein the animal is a mammalian animal.

31. (New) The method of claim 30, wherein the mammalian animal is a non-human primate.

32. (New) The method of claim 30, wherein the mammalian animal is a human.

33. (New) A method for repressing propagation of an immunodeficiency virus in an animal, the method comprising inoculating a

composition comprising a carrier and a Sendai virus vector encoding the virus protein.

34. (New) The method of claim 33, wherein the composition is inoculated by intranasal administration.

35. (New) The method of claim 33, wherein the composition is inoculated at least once by multiple dose administration.

36. (New) The method of claim 34, wherein the composition is inoculated at least once by multiple dose inoculation.

37. (New) The method of claim 35, wherein the method comprises the steps of (a) inoculating a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector.

38. (New) The method of claim 36, wherein the method comprises the steps of (a) inoculating a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector.

39. (New) The method of claim 37, wherein the genome is defective in env gene and nef gene.

40. (New) The method of claim 38, wherein the genome is defective in env gene and nef gene.

41. (New) The method of claim 33, wherein the virus protein comprises a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them.

42. (New) The method of claim 33, wherein the virus protein comprises Gag protein or a part of it.

43. (New) The method of claim 33, wherein the animal is a mammalian animal.

44. (New) The method of claim 43, wherein the mammalian animal is a non-human primate.

45. (New) The method of claim 43, wherein the mammalian animal is a human.

39. (New) The method of claim 37, wherein the genome is defective in env gene and nef gene.

40. (New) The method of claim 38, wherein the genome is defective in env gene and nef gene.

41. (New) The method of claim 33, wherein the virus protein comprises a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them.

42. (New) The method of claim 33, wherein the virus protein comprises Gag protein or a part of it.

43. (New) The method of claim 33, wherein the animal is a mammalian animal.

44. (New) The method of claim 43, wherein the mammalian animal is a non-human primate.

45. (New) The method of claim 43, wherein the mammalian animal is a human.

Claims Pending After Entry of Amendment

Claims 1-11 and 12-45 are now pending in the application.

1. (Amended) A vaccine comprising a Sendai virus vector encoding a virus protein of an immunodeficiency virus, wherein the virus protein comprises a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them, and wherein the vaccine induces a cellular immune response specific to the virus protein.

2. (Amended) A vaccine comprising a Sendai virus vector encoding a Gag protein or a part of it, wherein the vaccine induces a cellular immune response specific to the Gag protein or the part of it.

3. The vaccine of claim 1, wherein the Sendai virus vector is defective in V gene.

4. The vaccine of claim 2, wherein the Sendai virus vector is defective in V gene.

5. A method for vaccination, the method comprising inoculating a vaccine comprising a Sendai virus vector encoding a virus protein of an immunodeficiency virus.

6. The method of claim 5, wherein the vaccine is inoculated by intranasal administration.

7. The method of claim 5, wherein the vaccine is inoculated at least once in multiple vaccine inoculation.

8. The method of claim 6, wherein the vaccine is inoculated at least once in multiple vaccine inoculation.

9. (Amended) The method of claim 7, wherein the method comprises the steps of (a) inoculating a DNA vaccine comprising a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector encoding a virus protein of an immunodeficiency virus.

10. (Amended) The method of claim 8, wherein the method comprises the steps of (a) inoculating a DNA vaccine comprising a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector encoding a virus protein of an immunodeficiency virus.

11. (Amended) A method for inducing a cellular immune response specific to a virus protein of an immunodeficiency virus *in vitro*, the method

comprising the steps of (a) introducing a Sendai virus vector encoding the virus protein into an antigen presenting cell and (b) contacting the antigen presenting cell with a T helper cell and a cytotoxic T cell, thereby inducing the cellular immune response.

12. (New) The method of claim 11, wherein the virus protein comprises a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them.

13. (New) The method of claim 11, wherein the virus protein comprises Gag protein or a part of it.

14. (New) The method of claim 11, wherein the antigen presenting cell is an autologous herpesvirus papio-immortalized B lymphoblastoid cell.

15. (New) The method of claim 11, wherein said contacting step comprises co-culturing the antigen presenting cell with the T helper cell and the cytotoxic T cell in a medium.

16. (New) A composition comprising a carrier and a Sendai virus vector encoding a virus protein of an immunodeficiency virus, wherein the virus protein

comprises a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them, and wherein the vaccine induces cellular immune response specific to the virus protein.

17. (New) A composition comprising a carrier and a Sendai virus vector encoding Gag protein or a part of it, wherein the vaccine induces cellular immune response specific to the Gag protein or the part of it.

18. (New) The composition of claim 16, wherein the Sendai virus vector is defective in V gene.

19. (New) The composition of claim 17, wherein the Sendai virus vector is defective in V gene.

20. (New) A method for inducing cellular immune response specific to a virus protein of an immunodeficiency virus in an animal, the method comprising inoculating a composition comprising a carrier and a Sendai virus vector encoding the virus protein.

21. (New) The method of claim 20, wherein the composition is inoculated by intranasal administration.

22. (New) The method of claim 20, wherein the composition is inoculated at least once by multiple dose administration.

23. (New) The method of claim 21, wherein the composition is inoculated at least once by multiple dose inoculation.

24. (New) The method of claim 22, wherein the method comprises the steps of (a) inoculating a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector.

25. (New) The method of claim 23, wherein the method comprises the steps of (a) inoculating a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector.

26. (New) The method of claim 24, wherein the genome is defective in env gene and nef gene.

27. (New) The method of claim 25, wherein the genome is defective in env gene and nef gene.

28. (New) The method of claim 20, wherein the virus protein comprises

a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them.

29. (New) The method of claim 20, wherein the virus protein comprises Gag protein or a part of it.

30. (New) The method of claim 20, wherein the animal is a mammalian animal.

31. (New) The method of claim 30, wherein the mammalian animal is a non-human primate.

32. (New) The method of claim 30, wherein the mammalian animal is a human.

33. (New) A method for repressing propagation of an immunodeficiency virus in an animal, the method comprising inoculating a composition comprising a carrier and a Sendai virus vector encoding the virus protein.

34. (New) The method of claim 33, wherein the composition is

inoculated by intranasal administration.

35. (New) The method of claim 33, wherein the composition is inoculated at least once by multiple dose administration.

36. (New) The method of claim 34, wherein the composition is inoculated at least once by multiple dose inoculation.

37. (New) The method of claim 35, wherein the method comprises the steps of (a) inoculating a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector.

38. (New) The method of claim 36, wherein the method comprises the steps of (a) inoculating a DNA encoding the genome of the immunodeficiency virus and then (b) inoculating the Sendai virus vector.

39. (New) The method of claim 37, wherein the genome is defective in env gene and nef gene.

40. (New) The method of claim 38, wherein the genome is defective in env gene and nef gene.

41. (New) The method of claim 33, wherein the virus protein comprises a protein selected from the group consisting of Pol, gp41, Tat, Rev, Vpu, Vpx, Vpr, Vif, Nef, Gag-Pol fusion protein and a part of any of them.

42. (New) The method of claim 33, wherein the virus protein comprises Gag protein or a part of it.

43. (New) The method of claim 33, wherein the animal is a mammalian animal.

44. (New) The method of claim 43, wherein the mammalian animal is a non-human primate.

45. (New) The method of claim 43, wherein the mammalian animal is a human.